UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

DENISE DEMARS
Plaintiff

V.

COLOPLAST CORP., COLOPLAST A/S, and COLOPLAST MANUFACTURING US, LLC
Defendants

CIVIL ACTION

NO. _____

COMPLAINT AND JURY DEMAND

Plaintiff, Denise Demars, by and through her undersigned counsel, brings this action for damages against Defendants, Coloplast Corporation, Coloplast A/S, and Coloplast Manufacturing US, LLC, and alleges as follows:

I. PARTIES

A. Plaintiff

1. Plaintiff, Denise Demars is a citizen of Lowell, Middlesex County, Massachusetts.

B. Defendants

2. Defendant Coloplast Corporation ("Coloplast Corp.") is a corporation organized and existing under the laws of the State of Delaware, maintaining its principal place of business at 1601 West River Road North, Minneapolis, Minnesota 55411. Coloplast Corp. is a wholly owned U.S. sales and marketing subsidiary of Coloplast A/S.

3. Defendant, Coloplast A/S is a corporation organized and existing under the laws of the Kingdom of Denmark maintaining its principal place of business at Holtedam 1, Humleback 3050, Denmark and maintaining its North American principal place of business at 1601 West River Road North, Minneapolis, Minnesota 55411.

4. Defendant Coloplast Manufacturing US, LLC is a limited liability corporation organized and existing under the laws of the State of Delaware, maintaining its principal place of business at 1940 Commerce Drive, North Mankato, MN 56002. Its registered office is 560 Park Street, #6, St. Paul, Minnesota 55103. Coloplast Manufacturing US, LLC is a wholly-owned subsidiary of Coloplast Corp.

5. All acts and omissions of the above-referenced Defendants as described herein were done by its agents, servants, employees, and/or owners, acting in the course and scope of their respective agencies, services, employments, and/or ownership.

II. JURISDICTION AND VENUE

6. This Court has subject matter jurisdiction over the parties pursuant to 28 U.S.C. §1332(a) because the parties are citizens of different states and the amount in controversy exceeds $75,000.00, exclusive of interest and cost.

7. Venue for this action lies in the United States District Court of Massachusetts, because the Plaintiff resides in this District and the wrongful acts upon which this lawsuit is based occurred, in part, in this District. Venue is also proper pursuant to 28 U.S.C. §1391(c) because Defendants have substantial, systematic, and continuous contacts in the District of Massachusetts, and they are all subject to personal jurisdiction in this District.

III. Defendants' Pelvic Mesh Products

8. At all times material to this action, Defendants have designed, patented, manufactured, packaged, labeled, marketed, sold, and distributed a line of pelvic mesh products, which are delineated below. These products were designed primarily for the purposes of treating stress urinary incontinence and pelvic organ prolapse. Each of these products was cleared for sale in the United States after the Defendants made assertions to the Food and Drug

Administration of "Substantial Equivalence" under Section 510(k) of the Food, Drug and Cosmetic Act; this clearance process does not require the applicant to prove safety or efficacy. One or more of Defendants' pelvic mesh products was implanted in Plaintiff.

9. The products include those known as Supris-Suprapubic Sling System, T-Sling-Universal Polypropylene Sling, Aris-Transobturator Sling System, Novasilk-Synthetic Flat Mesh, Exair-Prolapse Repair System, and Minitape as well as any variations of these products and any unnamed Coloplast pelvic mesh product designed and sold for similar purposes, inclusive of the instruments and procedures for implementation. In addition, Coloplast manufactures, distributes, and sells products made of biologic materials known as Suspend-Tutoplast Processed Fascia Lata and Axis-Tutoplast Processed Dermis as well as any variations of these products and any unnamed Coloplast Pelvic Mesh Product designed and sold for similar purposes, inclusive of the instruments and procedures for implementation.

10. These products are collectively referenced as Defendants' "Pelvic Mesh Products" or "Products."

IV. Factual Background

11. At all relevant times, Defendants were in the business of developing, designing, licensing, manufacturing, distributing, selling, marketing, advertising, and delivering, and introducing into interstate commerce, including, *inter alia*, within the United States, either directly or indirectly through third parties, subsidiaries or related entities, Pelvic Mesh Products.

12. At all relevant times, Pelvic Mesh Products were used to treat pelvic organ prolapse and stress urinary incontinence.

13. A pelvic organ prolapse occurs when a pelvic organ, such as the bladder, drops ("prolapses") from its normal position and pushes against the walls of the vagina. Prolapse can

happen if the muscles that hold the pelvic organs in place become weak or stretched from childbirth or surgery. More than one pelvic organ can prolapse at the same time. Organs that can be involved in a pelvic organ prolapse include the bladder, the uterus, the bowel and the rectum.

14. Stress urinary incontinence is a type of incontinence characterized by leakage of urine during moments of physical stress.

15. Surgical mesh, including mesh used in Pelvic Mesh Products, is a medical device that is generally used to repair weakened or damaged tissue. It is made from porous absorbable or non-absorbable synthetic material or absorbable biologic material. In urogynecologic procedures, surgical mesh is permanently implanted to reinforce the weakened vaginal wall to repair pelvic organ prolapse or to support the urethra to treat urinary incontinence. Most Pelvic Mesh Products are comprised of non-absorbable, synthetic, monofilament polypropylene mesh and / or collagen.

16. Despite claims that polypropylene mesh is inert, the scientific evidence shows that this material as implanted in the Plaintiff is biologically incompatible with human tissue and when used as a woven or knitted alloplastic textile prosthetic mesh for pelvic floor repair, polypropylene and other surgical polymers promote a severe foreign body reaction and chronic inflammatory response in a large subset of the population implanted with Defendants' Pelvic Mesh Products. This "host defense response" by a woman's pelvic tissues promotes degradation of the polypropylene mesh and the pelvic tissue, and causes chronic inflammation of the pelvic tissue, shrinkage or contraction of the mesh leading to nerve entrapment, further inflammation, chronic infectious response and chronic pain. It also can cause new-onset painful sexual relations, significant urinary dysfunction, vaginal shortening and anatomic deformation, and can contribute to the formation of severe adverse reactions to the mesh.

17. Furthermore, Defendants' Pelvic Mesh Products containing collagen cause hyperinflammatory responses leading to problems including chronic pain and fibrotic reaction. Defendants' collagen-containing Products disintegrate after implantation into the female pelvis. The collagen-containing Products cause adverse tissue reactions, and are causally related to infection, as the collagen is a foreign organic material. Cross linked collagen is harsh upon the female pelvic tissues. It hardens the body.

18. When these Pelvic Mesh Products are inserted in the female body according to the manufacturers' instructions, it creates a non-anatomic condition in the pelvis leading to chronic pain and functional disabilities.

19. In 1996, the FDA cleared the first Pelvic Mesh Products for use in the treatment of stress urinary incontinence (SUI). These products include Products manufactured, marketed, and distributed by Defendants. These products are approved by the FDA under the abbreviated 510(k) approval process. Section 510(k) provides for marketing of a medical device if the device is deemed "substantially equivalent" to other predicate devices marketed before May 28, 1976. No formal review for safety or efficacy is required, and no formal review for safety or efficacy was ever conducted with regard to the Pelvic Mesh Products.

20. In May 2005, Mentor announced the U.S. launch of its new Aris(TM) Trans-Obturator Tape. According to Mentor's launch reports, "specifically designed to utilize Mentor's patented Trans-Obturator Technique (T.O.T.(TM)), Aris represents the newest technical achievement and advanced generation of trans-obturator slings for the treatment of stress urinary incontinence in women." "The introduction of Aris furthers Mentor's position as a pioneer of the trans-obturator method for treating stress incontinence in women," commented Joshua H. Levine, President and Chief Executive Officer of Mentor Corporation. "We are committed to

driving innovation in the field of women's health to provide better solutions for physicians and the patients they serve." Analytic Biosurgical Solutions ("ABISS") FDA registration lists its proprietary device as "Mentor Aris Trans-Obturator Tape and Surgical Kit."

21. On October 12, 2005, ABISS and Mentor entered into a number of agreements pursuant to which ABISS licensed a number of ABISS' products to Mentor, which were thereafter marketed by Mentor under its trademarks, including its Aris trademark. On June 2, 2006, Mentor sold its surgical, urological, clinical and consumer healthcare business segments to Coloplast for $461,145,398, including *inter alia*, Mentor's October 12, 2005 agreements with ABISS and Mentor's Aris and Novasilk Pelvic Mesh Products.

22. At all times, the product marketed and sold in the United States as "Mentor Aris Trans-Obturator Tape and Surgical Kit" was manufactured by ABISS and, at all times after October 2, 2006, the product "Mentor Aris Trans-Obturator Tape and Surgical Kit" was exclusively marketed and sold in the United States by Coloplast Corp. from its principal place of business in Minneapolis, Minnesota.

23. ABISS is registered with the FDA, Registration Number 3004756681, as the manufacturer of "Mentor Aris Trans-Obturator Tape and Surgical Kit."

24. On December 5, 2005, Mentor obtained 510(k) clearance for Mentor NovaSilk Mesh. Mentor NovaSilk Mesh is a permanent, synthetic knitted propylene mesh that is square in shape and is a sterile, single use device. The Mentor NovaSilk Mesh obtained 510(k) clearance based on substantial equivalence in material, function, performance, and design to the Gynemesh Prolene Soft (Polypropylene) Mesh cleared under 510(k) K013718 and knitted polypropylene already in use under Mentor's Aris Sling cleared under 510(k) K050148. Joshua H. Levine, President and Chief Executive Officer of Mentor Corporation commented, "The addition of

NovaSilk to Mentor's expanding portfolio of women's health products for pelvic organ prolapse or stress urinary incontinence reinforces the commitment of our urology franchise to surgeons and the patients they serve by providing high quality product offerings and customer service and support."

25. Coloplast Corp.'s annual report for 2009-2010 reported that "the majority of our acquired patents and trademarks are associated with the acquisition of Mentor's urology, business in 2006." The annual report also said that Mentor signed "a non-competition clause prohibiting Mentor (the seller) from selling urology products for the next seven years...."

26. Coloplast Corp. began marketing the Exair Prolapse Repair System in May 2009 to treat pelvic organ prolapse. This product is made of NovaSilk Mesh, precut into the necessary shape with four mesh arms extending from the main body, which are used to implant the device. This product obtained 510(k) clearance based on its substantial equivalence with Coloplast Corp.'s (formerly Mentor's) NovaSilk Mesh, and Gynecare Prolift Total Pelvic Floor Repair System cleared under pre-market notification number K071512 on May 15, 2008.

27. Coloplast A/S received 510(k) clearance for the Supris Retropubic Sling System 510(k) K111233 in June 2011, as a device substantially equivalent to the Mentor Aris Suprapubic Surgical Kit.

28. On October 29, 2010, Coloplast Corp. acquired Mpathy Medical Devices, Inc. ("Mpathy"). Mpathy was founded in 2003, with the aim of developing less invasive surgical solutions for the treatment of female stress urinary incontinence and pelvic organ prolapse. Mpathy's core product lines included Minitape® and Omnisure® for stress urinary incontinence, and the Restorelle® family for pelvic organ prolapse. Defendant Coloplast Corp. said of the acquisition that Coloplast Corp.'s market position in Surgical Urology and Female Pelvic Health

would immediately strengthen based on Mpathy's product portfolio including slings, mini-slings and meshes for stress urinary incontinence and pelvic floor repair and material portfolio including Smartmesh® technology.

29. Coloplast Corp.'s website describes its various products, including those for treating (i) "Pelvic Organ Prolapse" and (ii) "Stress Urinary Incontinence," including "Sling Procedures." A press release issued by Coloplast Corp. described Coloplast Corp.'s new corporate headquarters at 1601 West River Road in Minneapolis and stated that "Denmark-based Coloplast…selected north Minneapolis as the new home for its North American headquarters in 2006." According to the press release the new headquarters "will include one of the company's three global Innovation Centers."

30. On July 13, 2011, the FDA issued a new warning regarding serious complications associated with Pelvic Mesh Products, such as the Products manufactured, marketed, and distributed by Defendants. In this warning, the FDA indicated that "serious complications associated with surgical mesh for transvaginal repair of POP are **not rare**." (emphasis in the original). The FDA had also received increased reports of complications associated with the Pelvic Mesh Products used in both pelvic organ prolapse and stress urinary incontinence cases.

31. The FDA Safety Communication also stated, *"Mesh contraction* (shrinkage) is a *previously unidentified risk of* transvaginal POP repair with mesh that has been reported in the published scientific literature and in adverse event reports to the FDA . . . Reports in the literature associate mesh contraction with vaginal shortening, vaginal tightening and vaginal pain." (emphasis in original).

32. The FDA Safety Communication further indicated that the benefits of using Pelvic Mesh Products instead of other feasible alternatives did not outweigh the associated risks.

Specifically, the FDA Safety Communication stated: "it is not clear that transvaginal POP repair with mesh is more effective than traditional non-mesh repair in all patients with POP and it may expose patients to greater risks."

33. Contemporaneously with the Safety Communication, the FDA released a publication titled "Urogynecologic Surgical Mesh: Update on the Safety and Effectiveness of Transvaginal Placement for Pelvic Organ Prolapse" (the "White Paper"). In the White Paper, the FDA noted that published, peer-reviewed literature demonstrates that "[p]atients who undergo POP repair with mesh are subject to mesh-related complications that are not experienced by patients who undergo traditional surgery without mesh."

34. The FDA summarized its findings from its review of the adverse event reports and applicable literature stating that it "has NOT seen conclusive evidence that using transvaginally placed mesh in POP repair improves clinical outcomes any more than traditional POP repair that does not use mesh, and it may expose patients to greater risks." (Emphasis in original).

35. The White Paper further stated that "these products are associated with serious adverse events . . . Compounding the concerns regarding adverse events are performance data that fail to demonstrate improved clinical benefit over traditional non-mesh repair." In its White Paper, the FDA advises doctors to, *inter alia*, "[r]ecognize that in most cases POP can be treated successfully without mesh thus avoiding the risk of mesh related complications." The White Paper concludes by stating that the FDA "has identified serious safety and effectiveness concerns over the use of surgical mesh for the transvaginal repair of pelvic organ prolapse."

36. On August 25, 2011, Public Citizen, a consumer advocacy group, submitted a petition to the FDA seeking to ban the use of Pelvic Mesh Products in pelvic repair procedures.

In its Petition, Public Citizen warned that Pelvic Mesh Products should be recalled because they offer no significant benefits, but expose patients to serious risks and the potential for permanent life-altering harm. Joining Public Citizen as co-petitioners were Dr. L. Lewis Wall, a professor of obstetrics and gynecology at Washington University in St. Louis, and Dr. Daniel S. Elliott, a urologic surgeon specializing in female urology at the Mayo Clinic in Rochester, Minnesota.

37. In a December 2011 Joint Committee Opinion, the American College of Obstetricians and Gynecologists ("ACOG") and the American Urogynecologic Society ("AUGS") also identified physical and mechanical changes to the transvaginal mesh inside the body as a serious complication associated with transvaginal mesh, stating:

> There are increasing reports of vaginal pain associated with changes that can occur with mesh (contraction, retraction, or shrinkage) that result in taut sections of mesh . . . Some of these women will require surgical intervention to correct the condition, and some of the pain appears to be intractable.

38. The ACOG/AUGS Joint Committee Opinion also recommended, among other things, that "[p]elvic organ prolapse vaginal mesh repair should be reserved for high-risk individuals in whom the benefit of mesh placement may justify the risk."

39. As is known to the Defendants, the risks associated with POP repair are the same as SUI repair. However, the data regarding the magnitude and frequency of these known risks are not as developed as the data on POP repair. The FDA recognized this, as demonstrated by its Section 522 Orders issued to manufacturers of Pelvic Mesh Products used to treat SUI in January of 2012.

40. In September 2011, the FDA acknowledged the need for additional data and noted in "Surgical Mesh For Treatment of Women with Pelvic Organ Prolapse and Stress Urinary Incontinence" that the literature and information developing on SUI repair with Pelvic Mesh

Products "indicate[] that serious complications can occur . . . [and] a case can be made for additional premarket and/or post market studies to better address the risk/benefit of all mesh products used for SUI."

41. Defendants did not, and have not, adequately studied the extent of the risks associated with the Products. In January 2012, the FDA recognized the risk to women and mandated additional studies to further investigate these risks.

42. Defendants knew or should have known that the Products unreasonably exposed patients to the risk of serious harm while conferring no benefit over available feasible alternatives that do not involve the same risks. At the time Defendants began marketing its Pelvic Mesh Products, Defendants were aware that its Pelvic Mesh Products were associated with each and every one of the adverse events communicated by the FDA in its July 13, 2011, safety communication. Despite claims that polypropylene mesh is inert, the scientific evidence shows that this material as implanted in the Plaintiff set forth below is biologically incompatible with human tissue and when used as a woven or knitted alloplastic textile prosthetic mesh for pelvic floor repair, polypropylene and other surgical polymers promote a severe foreign body reaction and chronic inflammatory response in a large subset of the population implanted with Defendants' Pelvic Mesh Products. This "host defense response" by a woman's pelvic tissues promotes degradation of the polypropylene mesh and the pelvic tissue, causes chronic inflammation of the pelvic tissue, causes shrinkage or contraction of the mesh leading to nerve entrapment, further inflammation, chronic infectious response and chronic pain, cause new-onset painful sexual relations, significant urinary dysfunction, vaginal shortening and anatomic deformation, and can contribute to the formation of severe adverse reactions to the polypropylene mesh.

43. The FDA defines both "degradation" and "fragmentation" as "device problems" to which the FDA assigns a specific "device problem code." "Material Fragmentation" is defined as an "[i]ssue associated with small pieces of the device breaking off unexpectedly" and "degraded" as an "[i]ssue associated with a deleterious change in the chemical structure, physical properties, or appearance in the materials that are used in device construction."

44. Complications from mesh placement for pelvic organ prolapse include among other adverse events: acute and chronic infection, tissue contraction due to mesh shrinkage, erosion of the mesh into adjacent structures, and dyspareunia. 15 Cosson, M., et al., *Mechanical properties of synthetic implants used in the repair of prolapse and urinary incontinence in women: which is the ideal material?* Int Urogynecol J Pelvic Floor Dysfunct, 2003. **14**(3): p. 169-78; discussion 178. Jones, K.A., et al., *Tensile properties of commonly used prolapse meshes.* Int Urogynecol J Pelvic Floor Dysfunct, 2009. **20**(7): p. 847-53. Margulies, R.U., et al., *Complications requiring reoperation following vaginal mesh kit procedures for prolapse.* Am J Obstet Gynecol, 2008. **199**(6): p. 678 e1-4.

45. The Products were unreasonably susceptible to degradation and fragmentation inside the body; shrinkage or contraction inside the body; intense foreign body reaction; chronic inflammatory response; chronic wound healing; chronic infections in and around the mesh fibers; nerve entrapment in the collagen scar formation. Defendants knew or should have known of these serious risks and should have, therefore, warned physicians and patients regarding these risks; to the extent they were known or knowable.

46. To this day, the Products continue to be marketed to the medical community and to patients as safe, effective and reliable medical devices, implanted by safe, effective and minimally invasive surgical techniques, and as safer and more effective as compared to available feasible alternative treatments of pelvic organ prolapse and stress urinary incontinence, and other competing products.

47. Defendants omitted and downplayed the risks, dangers, defects, and disadvantages of the Products, and advertised, promoted, marketed, sold and distributed the Products as safe medical devices when Defendants knew or should have known that the Products were not safe for their intended purposes, and that the Products would cause, and did cause, serious medical problems, and in some patients, including the Plaintiff, catastrophic injuries. Further, while some of the problems associated with the Products were made known to physicians, the magnitude and frequency of these problems were not disclosed and were hidden from physicians.

48. Contrary to Defendants' representations and marketing to the medical community and to the patients themselves, the Products have high rates of failure, injury, and complications, fail to perform as intended, require frequent and often debilitating re-operations, and have caused severe and irreversible injuries, conditions, and damage to a significant number of women, including the Plaintiff, making them defective under the law.

49. The specific nature of the Products' defects includes, but is not limited to, the following:

a. The use of polypropylene in the Products and the adverse tissue reactions and host defense response that result from such material, causing adverse reactions and serious, permanent injuries including, but not limited to, painful recurrent erosions and associated intractable pain;

b. The design of the Products to be inserted into and through an area of the body that is blood vessel rich, nerve dense, and bacteria laden leading to excessive blood loss and vascular damage, permanent nerve injury and associated chronic, intractable neuropathic pain, contaminated permanently-implanted

mesh causing chronic infections, subclinical infections and biofilms, enhanced chronic inflammatory response, chronic wound healing with tissue destruction, as well as numerous other adverse reactions and serious and permanent injuries;

c. Biomechanical issues with the design of the Products which result in a nonanatomic condition leading to contraction or shrinkage of the mesh inside the body, that in turn causes surrounding tissue to become eroded, inflamed, fibrotic and infected, resulting in serious and permanent injury;

d. The propensity of the mesh design characteristics of the Products for plastic deformation when subjected to tension both during implantation and once implanted inside the body which causes the mesh, or portions thereof, to be encapsulated in a rigid scar plate which leads to nerve entrapment, bacterial entrapment, tissue destruction, enhanced inflammatory and fibrotic response and chronic pain;

e. The propensity of the Products to become rigid and inflexible, causing them to be improperly mated to the delicate and sensitive areas of the vagina and pelvis where they are implanted, and causing discomfort and pain with normal daily activities that involve movement in the pelvic region (e.g., intercourse, defecation, walking);

f. The propensity of the Products for degradation or fragmentation over time, which causes an increased surface area that leads to enhanced chronic inflammatory and fibrotic reaction, causes a "barbed wire" or "saw blade" effect by the fragmented surface "sawing" through the tissue, leads to bacteria

harboring in the fragmented, peeled and split fiber surface which in turn leads to chronic infections at the mesh surface, and results in continuing injury over time; and

g. The hyper-inflammatory responses to collagen leading to problems including chronic inflammatory response, chronic pain and fibrotic reaction as well as infections and other serious adverse events;

h. The propensity of the collagen products to disintegrate after implantation in the female pelvis, causing pain and other adverse reactions;

i. The harshness of collagen upon the female pelvic tissue, and the hardening of the product in the body; and

j. The inability of surgeons to effectively treat many of these conditions due to the integration of the mesh into the pelvic tissue and thus the inability to safely remove or excise the mesh once a complication occurs;

50. The Products are also defective due to Defendants' failure to adequately warn or instruct the Plaintiff and/or her health care providers of subjects including, but not limited to, the following:

a. The Products' propensities to contract, retract, and/or shrink inside the body;

b. The Products' propensities for degradation, fragmentation and/or migration;

c. The Products' inelasticity preventing proper mating with the pelvic floor and vaginal region;

d. The frequency and manner of transvaginal mesh erosion or extrusion;

e. The risk of chronic inflammation resulting from the Products;

f. The risk of chronic infections resulting from the Products;

g. The risk of permanent vaginal or pelvic scarring as a result of the Products;

h. The risk of de novo urinary dysfunction;

i. The risk of de novo dyspareunia or painful sexual relations;

j. The risk of recurrent, intractable pelvic pain and other pain resulting from the Products;

k. The need for corrective or revision surgery to adjust or remove the Products which in some cases is not feasible nor possible;

l. The severity of complications that could arise as a result of implantation of the Products;

m. The hazards associated with the Products;

n. The Products' defects described herein;

o. Treatment of pelvic organ prolapse and stress urinary incontinence with the Products is no more effective than feasible, available and safer alternatives;

p. Treatment of pelvic organ prolapse and stress urinary incontinence with the Products exposes patients to greater risk than feasible, available and safer alternatives;

q. Treatment of pelvic organ prolapse and stress urinary incontinence with the Products makes future surgical repair more difficult than feasible, available and safer alternatives;

r. Use of the Products puts the patient at greater risk of requiring additional surgery than feasible, available and safer alternatives;

s. Removal of the Products due to complications may involve multiple surgeries and may significantly impair the patient's quality of life; and

t. Complete removal of the Products may not be possible and may not result in complete resolution of the complications, including pain; and

As a result of these life-altering and, in some cases, permanent injuries, Plaintiff has suffered severe emotional pain and injury and has suffered and will suffer apprehension of increased risk for injuries, infections, pain, mental anguish, discharge, and multiple corrective surgeries as a result of implantation of mesh.

51. Defendants under reported and continue to underreport information about the propensity of the Products to fail and cause injury and complications, and have made unfounded representations regarding the efficacy and safety of the Products through various means and media.

52. Defendants under reported and continue to underreport information about the propensity of the Products to fail and cause injury and complications, and have made unfounded representations regarding the efficacy and safety of the Products through various means and media.

53. Defendants failed to perform proper and adequate testing and research in order to determine and evaluate the nature, magnitude and frequency of the risks attendant to the Products.

54. Defendant(s) failed to design and establish a safe, effective procedure for removal of the Products, or to determine if a safe, effective procedure for removal of the Products exists.

55. Feasible, suitable and safer alternatives to the Products have existed at all times relevant that do not present the same frequency or severity of risks as do the Products.

56. The Products were at all times utilized and implanted in a manner foreseeable to Defendants, as Defendants generated the instructions for use, created the procedures for implanting the devices, and trained the implanting physician.

57. Defendants knowingly provided incomplete and insufficient training and information to physicians regarding the use of the Products and the aftercare of patients implanted with the Product.

58. As a result of these life-altering and, in some cases, permanent injuries, Plaintiff has suffered severe emotional pain and injury and has suffered and will suffer apprehension of increased risk for injuries, infections, pain, mental anguish, discharge, and multiple corrective surgeries as a result of implantation of mesh.

59. The Product implanted in the Plaintiff was in the same or substantially similar condition as it was when it left Defendants' possession, and in the condition directed by and expected by Defendants. The injuries, conditions, and complications suffered by numerous women around the world who have been implanted with the Products include, but are not limited to, erosion, mesh contraction, infection, fistula, inflammation, scar tissue, organ perforation, dyspareunia (pain during sexual intercourse), urinary dysfunction, blood loss, neuropathic and other acute and chronic nerve damage and pain, pudendal nerve damage, pelvic floor damage, and chronic pelvic pain. As a result of these life-altering and, in some cases, permanent injuries, Plaintiff has suffered severe emotional pain and injury and has suffered and will suffer apprehension of increased risk for injuries, infections, pain, mental anguish, discharge, and multiple corrective surgeries as a result of implantation of Pelvic Mesh Products.

60. In many cases, including the Plaintiff, women have been forced to undergo extensive medical treatment including, but not limited to, operations to locate and remove mesh,

operations to attempt to repair pelvic organs, tissue, and nerve damage, the use of pain control and other medications, injections into various areas of the pelvis, spine, and the vagina, and operations to remove portions of the female genitalia.

61. The medical and scientific literature studying the effects of the Products, like that of the Product implanted in the Plaintiff, has examined each of these injuries, conditions, and complications, and has reported that they are causally related to the Products.

62. Removal of contracted, eroded and/or infected transvaginal mesh can require multiple surgical interventions for removal of mesh and results in scarring on fragile compromised pelvic tissue and muscles.

63. At all relevant times herein, Defendants continued to promote the Products as safe and effective even when no clinical trials had been done supporting long- or short-term efficacy or safety.

64. In doing so, Defendants failed to disclose the known risks and failed to warn of known or scientifically knowable dangers and risks associated with the Products, including the magnitude and frequency of these risks.

65. At all relevant times herein, Defendants failed to provide sufficient warnings and instructions that would have put the Plaintiff and the general public on notice of the dangers and adverse effects caused by implantation of the Products.

66. The Products as designed, manufactured, distributed, sold and/or supplied by Defendants were defective as marketed due to inadequate warnings, instructions, labeling and/or inadequate testing in the presence of Defendants' knowledge of lack of safety.

67. The injuries, conditions, and complications suffered by numerous women around the world who have been implanted with the Products include, but are not limited to, erosion,

mesh contraction, infection, fistula, inflammation, scar tissue, organ perforation, dyspareunia (pain during sexual intercourse), blood loss, neuropathic and other acute and chronic nerve damage and pain, pudendal nerve damage, pelvic floor damage, chronic pelvic pain, emotional distress and mental anguish, and other debilitating complications. In addition, Plaintiff will need to be continuously monitored as a result of being implanted with Defendants' Product. A monitoring procedure exists for individuals experiencing physical and mental injuries from mesh implanted in patients with pelvic organ prolapsed and/or stress urinary incontinence. The monitoring procedure has been prescribed by a qualified physician and is reasonably necessary according to contemporary scientific principles. As such, Plaintiff is entitled to future medical monitoring and treatment directly related to the existing injuries caused by the defective products.

68. In many cases, including the Plaintiff, the women have been forced to undergo extensive medical treatment, including, but not limited to, operations to locate and remove mesh, operations to attempt to repair pelvic organs, tissue, and nerve damage, the use of pain control and other medications, injections into various areas of the pelvis, spine, and the vagina, and operations to remove portions of the female genitalia.

69. The medical and scientific literature studying the effects of Defendants' Pelvic Mesh Products, like that of the product(s) implanted in the Plaintiff, has examined each of these injuries, conditions, and complications, and has reported that they are causally related to the Products.

70. Removal of contracted, eroded and/or infected transvaginal mesh can require multiple surgical interventions for removal of mesh and results in scarring on fragile compromised pelvic tissue and muscles.

71. At all relevant times herein, Defendants continued to promote the Products as safe and effective even when no clinical trials had been done supporting long- or short-term efficacy.

72. In doing so, Defendants failed to disclose the known risks and failed to warn of known or scientifically knowable dangers and risks associated with the Products.

73. At all relevant times herein, Defendants failed to provide sufficient warnings and instructions that would have put the Plaintiff and the general public on notice of the dangers and adverse effects caused by implantation of the Products.

74. The Products as designed, manufactured, distributed, sold and/or supplied by Defendants were defective as marketed due to inadequate warnings, instructions, labeling and/or inadequate testing in the presence of Defendants' knowledge of lack of safety.

V. CASE SPECIFIC ALLEGATIONS

75. The Plaintiff underwent surgery on or about January 28, 2010, at which time the Coloplast Supris-Suprapubic Sling System was implanted.

76. On or about November 23, 2016, the Plaintiff underwent additional surgery which consisted of excision of Supra Pubic Sinus tract and Supra Pubic Removal of Vaginal Mesh. It was at this time that Plaintiff was made aware of the negligence and/or breach of warranty by the Defendants.

77. Plaintiff is likely to have additional surgery in the future.

VI. CAUSES OF ACTION

COUNT I: PRODUCT LIABILITY- DEFECTIVE MANUFACTURE AND DESIGN

Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein.

78. One or more of the defects in the Products are a result of improper or incorrect manufacturing processes that result in the Products as manufactured deviating from its intended

design. The defects caused by improper or incorrect manufacturing rendered the Products unreasonably dangerous, deficient, and defective to consumers and to Plaintiff. The defects in the Products implanted in Plaintiff existed from their manufacture, therefore the defects were present when they left the possession and control of Coloplast.

79. Coloplast's Pelvic Mesh Products were defective, unfit, unsafe, inherently dangerous and unreasonably dangerous for their intended and reasonably foreseeable uses. These Products were in said condition when they entered the stream of commerce and were received by Plaintiff. The Products do not meet or perform to the expectations of patients and their health care providers. Coloplast's Products were dangerous to an extent beyond that which would be contemplated by the ordinary consumer.

80. The Products create a risk to the health and safety of the patients that are far more significant and devastating than the risks posed by other products and procedures available to treat the corresponding medical conditions, and which far outweigh the utility of the Products.

81. Coloplast has intentionally and recklessly designed, manufactured, marketed, labeled, sold and distributed the Products with wanton and willful disregard for the health of the Plaintiff and others, and with malice, placing their economic interest above the health and safety of the Plaintiff.

82. The Products used by Plaintiff's physicians were not substantially changed, modified, or altered at any time in any manner whatsoever prior to use. The subject Products reached the Plaintiff in such a condition that was unreasonably dangerous to her. The Coloplast Pelvic Mesh was used in the manner for which it was intended. This use resulted in injury to Plaintiff.

83. At no time did Plaintiff have reason to believe that the Pelvic Mesh Product was in a condition not suitable for its proper and intended use among patients.

84. Plaintiff was not able to discover, nor could she have discovered through the exercise of reasonable care, the defect of the Products. Furthermore, in no way could Plaintiff have known that Coloplast had manufactured the Product in such a way as to increase the risk of harm or injury to the patient receiving the implant.

85. As a direct and proximate result of Coloplast's wrongful conduct, including Coloplast's design, manufacture, labeling, marketing, sale and distribution of Pelvic Mesh Products, Plaintiff has sustained and will continue to sustain severe and debilitating injuries, serious bodily injury, mental and physical pain and suffering, and has incurred economic loss.

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and request compensatory damages together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT II: PRODUCT LIABILITY – FAILURE TO WARN

Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein.

86. The Products were defective by reason of failure of Coloplast to provide an adequate warning or instructions.

87. Coloplast failed to properly and adequately warn and instruct the Plaintiff and/or her health care providers as to the risks and benefits of Coloplast's Pelvic Mesh Products.

88. Coloplast failed to properly and adequately warn and instruct the Plaintiff and/or her health care providers with regard to the inadequate research and testing of the Pelvic Mesh Products, and the lack of a safe, effective procedure for removal of the Products.

89. Coloplast failed to provide such adequate warning or instruction that a manufacturer exercising reasonable care would have provided to physicians who implanted the Products or to the women who had been implanted with the Products, concerning the following risks. Coloplast had actual or constructive knowledge of the following risks at the time the Products left Coloplast's control and were being marketed:

a. The high failure rate of the Products;

b. The high rate of infection and abscesses caused by the Products;

c. The high rate of vaginal erosions and extrusions caused by the Products;

d. The high rate of chronic pain caused by the Products;

e. The necessity to remove the Products from the patient's body in the event of product failure, infections, abscesses, erosion, extrusion, or other complications; and

f. The difficulty in removing the Products from the patient's body, including the complete lack of a safe, effective procedure for removal of the Pelvic Mesh Products.

90. After receiving notices of numerous bodily injuries resulting from the Products, Coloplast failed to provide such post-marketing or post-sale warnings or instructions that a manufacturer exercising reasonable care should have provided to physicians who implanted the Products or those women who had been implanted with the Products that the products were causing an unreasonably high rate of complications such as mesh erosion, extrusion/protrusion,

chronic pain, mesh contraction, infection, abscesses, fistula, inflammation, scar tissue, organ perforation, dyspareunia, bleeding, neuropathic and other acute and chronic nerve damage and pain, vaginal scarring, vaginal shrinkage, pelvic floor damage, pelvic pain, urinary and fecal problems, and prolapse organs. Furthermore, Coloplast failed to provide post-marketing or post-sale warnings or instructions concerning the necessity to remove the Products from the patient's body in the event of the product failure or other complications.

91. Coloplast intentionally, recklessly, and maliciously misrepresented the safety, risks and benefits of the Coloplast Pelvic Mesh Products, understating the risks and exaggerating the benefits in order to advance their own financial interests, with wanton and willful disregard for the rights and health of the Plaintiff.

92. Absence of a warning or instruction renders the product unreasonably dangerous for its intended use.

93. Coloplast is strictly liable in tort to the Plaintiff for their wrongful conduct pursuant to common law.

94. As a direct and proximate result of Coloplast's wrongful conduct, including Coloplast's wrongful design, manufacture, marketing, sale and distribution of the pelvic Mesh Products, both at the time of marketing and after the sale of the Products, Plaintiff has sustained and will continue to sustain severe and debilitating injuries, serious bodily injury, mental and physical pain and suffering and has incurred economic loss.

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and request compensatory damages together

with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT III: NEGLIGENCE

Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein.

95. Defendants had a duty to individuals, including Plaintiff, to use reasonable care in designing, researching, manufacturing, marketing, labeling, packaging, supplying, distributing and selling the Products.

96. Defendants were negligent in failing to use reasonable care as described herein in designing, manufacturing, marketing, labeling, packaging and selling the Products. Defendants breached their duty by:

a. Failing to design the Products so as to avoid unreasonable risk of harm to women in whom the Products were implanted, including Plaintiff;

b. Failing to manufacture the Products so as to avoid an unreasonable risk of harm to women in whom the Products were implanted, including Plaintiff;

c. Failing to use reasonable care in the testing of the Products so as to avoid an unreasonable risk of harm to women in whom the Products were implanted, including Plaintiff;

d. Failing to use reasonable care in inspecting the Products so as to avoid an unreasonable risk of harm to women in whom the Products were implanted, including Plaintiff;

e. Otherwise negligently or carelessly designing, manufacturing, marketing, labeling, packaging and/or selling the Products.

97. The reasons that Defendants' negligence caused the Products to be unreasonably dangerous and defective include, but are not limited to:

a. the use of polypropylene material in the Products and the immune reaction that results from such material, causing adverse reactions and injuries;

b. the design of the Products to be inserted into and through an area of the body with high levels of bacteria that adhere to the mesh causing immune reactions and subsequent tissue breakdown and adverse reactions and injuries;

c. biomechanical issues with the design of the Products, including, but not limited to, the propensity of the Products to contract or shrink inside the body, that in turn cause surrounding tissue to be inflamed, become fibrotic, and contract, resulting in injury;

d. the use and design of arms and anchors in the Products, which, when placed in the women, are likely to pass through contaminated spaces and injure major nerve routes in the pelvic region;

e. the propensity of the Products for migration or to gradually elongate and deform when subject to prolonged tension inside the body;

f. the inelasticity of the Products, causing them to be improperly mated to the delicate and sensitive areas of the pelvis where they are implanted, and causing pain upon normal daily activities that involve movement in the pelvis (e.g., intercourse, defecation);

g. the propensity of the Products for degradation or fragmentation over time, which causes a chronic inflammatory and fibrotic reaction, and results in continuing injury over time;

h. the propensity of the Products to cause long standing inflammatory response altering the effective porosity of the mesh resulting in poor outcomes including bridging fibrosis, compromise of tissues in contact with or surrounding the mesh, erosion, nerve damage and resulting neuromas.

i. the creation of a non-anatomic condition in the pelvis leading to chronic pain and functional disabilities when the mesh is implanting according to the manufacturers' instructions.

98. Defendants also negligently failed to warn or instruct the Plaintiff and/or her health care providers of subjects including, but not limited to, the following:

a. The Products' propensities to contract, retract, and/or shrink inside the body;

b. The Products' propensities for degradation, fragmentation and/or migration;

c. The Products' inelasticity preventing proper mating with the pelvic floor and vaginal region;

d. The frequency and manner of mesh erosion or extrusion;

e. The risk of chronic inflammation resulting from the Products;

f. The risk of chronic infections resulting from the Products;

g. The risk of permanent vaginal or pelvic scarring as a result of the Products;

h. The risk of de novo urinary dysfunction;

i. The risk of de novo dyspareunia or painful sexual relations;

j. The risk of recurrent, intractable pelvic pain and other pain resulting from the Products;

k. The need for corrective or revision surgery to adjust or remove the Products which in some cases is not feasible nor possible;

l. The severity of complications that could arise as a result of implantation of the Products;

m. The hazards associated with the Products;

n. The Products' defects described herein;

o. Treatment of pelvic organ prolapse and stress urinary incontinence with the products is no more effective than feasible, available and safer alternatives;

p. Treatment of pelvic organ prolapse and stress urinary incontinence with the Products exposes patients to greater risk than feasible, available and safer alternatives;

q. Treatment of pelvic organ prolapse and stress urinary incontinence with the Products makes future surgical repair more difficult than feasible, available and safer alternatives;

r. Use of the Products puts the patient at greater risk of requiring additional surgery than feasible, available and safer alternatives;

s. Removal of the Products due to complications may involve multiple surgeries and may significantly impair the patient's quality of life; and

t. Complete removal of the Products may not be possible and may not result in complete resolution of the complications, including pain; and

a. As a result of these life-altering and, in some cases, permanent injuries, Plaintiff has suffered severe emotional pain and injury and has suffered and will suffer apprehension of increased risk for injuries, infections, pain, mental anguish, discharge, and multiple corrective surgeries as a result of implantation of mesh.

99. Defendants likewise failed to conduct post-market vigilance or surveillance by:

a. Monitoring or acting on findings in the scientific and medical literature;

b. Monitoring or investigating and evaluating reports in the FDA adverse event databases for their potential significance for Defendants' Pelvic Mesh Products; and

c. Failing to comply with manufacturer requirements of the Medical Device Reporting (MDR) Regulations, specifically:

i. Failing to report MDRs (Medical Device [adverse event] Reports); and

ii. Failing to investigate reports of serious adverse events.

100. As a direct and proximate result of Defendants' negligence, Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and will likely undergo further medical treatment and procedures, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, lost income, and other damages.

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and request compensatory damages together

with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT IV: BREACH OF EXPRESS WARRANTY

Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein.

101. Defendants made assurances as described herein to the general public, hospitals and health care professionals that the Products were safe and reasonably fit for their intended purposes.

102. Plaintiff and/or her healthcare provider chose the Product based upon Defendants' warranties and representations as described herein regarding the safety and fitness of the Product.

103. Plaintiff, individually and/or by and through her physician, reasonably relied upon Defendants' express warranties and guarantees that the Products were safe, merchantable, and reasonably fit for their intended purposes.

104. Defendants breached these express warranties because the Product implanted in Plaintiff was unreasonably dangerous and defective as described herein and not as Defendants had represented.

105. Defendants' breach of their express warranties resulted in the implantation of an unreasonably dangerous and defective product in the body of the Plaintiff, placing said Plaintiff's health and safety in jeopardy.

106. As a direct and proximate result of Defendants' breach of the aforementioned express warranties, the Plaintiff has experienced significant mental and physical pain and

suffering, has sustained permanent injury, has undergone medical treatment and will likely undergo further medical treatment and procedures, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, and/or lost income, and other damages.

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and request compensatory damages together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT V: BREACH OF IMPLIED WARRANTY

Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein.

107. Defendants impliedly warranted that the Products were merchantable and were fit for the ordinary purposes for which they were intended.

108. When the Products were implanted in the Plaintiff to treat her pelvic organ prolapse and/or stress urinary incontinence, the Product was being used for the ordinary purposes for which they were intended.

109. The Plaintiff, individually and/or by and through her physician, relied upon Defendants' implied warranties of merchantability in consenting to have the Products implanted in her.

110. Defendants breached these implied warranties of merchantability because the Product implanted in the Plaintiff was neither merchantable nor suited for their intended uses as warranted.

111. Defendants' breach of their implied warranties resulted in the implantation of unreasonably dangerous and defective Product in the body of the female Plaintiff, placing said Plaintiff's health and safety in jeopardy.

112. As a direct and proximate result of Defendants' breach of the aforementioned implied warranties, the Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and will likely undergo further medical treatment and procedures, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, and/or lost income, and other damages.

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and request compensatory damages together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT VI: NEGLIGENT MISREPRESENTATION

Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein.

113. Defendants had a duty to accurately and truthfully represent to the medical and healthcare community, Plaintiff, and the public, that the Pelvic Mesh Products had not been adequately tested and found to be safe and effective for the treatment of incontinence and prolapse. The representations made by Defendants, in fact, were false.

114. Defendants failed to exercise ordinary care in the representations concerning the Pelvic Mesh Products while they were involved in their manufacture, sale, testing, quality

assurance, quality control, and distribution in interstate commerce, because Defendants negligently misrepresented the Pelvic Mesh Products' high risk of unreasonable, dangerous, adverse side effects.

115. Defendants breached their duty in representing that the Defendants' Pelvic Mesh Products have no serious side effects different from older generations of similar products and/or procedures to Plaintiff, Plaintiff's physicians, and the medical and healthcare community.

116. As a foreseeable, direct and proximate result of the negligent misrepresentation of Defendants as set forth herein, Defendants knew, and had reason to know, that the Pelvic Mesh Products had been insufficiently tested, or had not been tested at all, and that they lacked adequate and accurate warnings, and that they created a high risk, and/or higher than acceptable risk, and/or higher than reported and represented risk, of adverse side effects, including, erosion, pain and suffering, surgery to remove the Products, and other severe and personal injuries, which are permanent and lasting in nature.

117. As a direct and proximate result of the Defendants' conduct, Plaintiff has been injured, and sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and consortium, economic damages, and death.

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and request compensatory damages together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT VII: VIOLATION OF CONSUMER PROTECTION LAW M.G.L. c. 93(A)

Plaintiff incorporates all of the preceding paragraphs of this Complaint as if fully set forth here and further alleges as follows:

118. At all relevant times hereto the Defendants were engaged in trade or commerce.

119. The acts of the defendants alleged in Counts I through VI constitute unfair or deceptive acts or practices within the meaning of G.L. c. 93A, §§ 2 and 3, 940 C.M.R. 3.05(1), and 940 C.M.R. 3.16(1) and (2).

120. The actions of the Defendants described herein were performed willfully and knowingly.

121. As a result of the unfair or deceptive acts or practices described in Counts I through VI, the Plaintiff, Denise Demars, sustained injury including but not limited to the injuries detailed above, incorporated herein.

122. On February 6, 2018 the Plaintiff, through her attorneys, sent the Defendants, via UPS, a written demand for relief pursuant to M.G.L. c.93A, §9(3), identifying the claimant and reasonably describing the unfair and deceptive acts or practices relied upon and the injuries suffered.

123. As of the present date, over 30 days have elapsed since service of Plaintiff's demand and there has been no satisfactory response by the Defendant, in violation of the requirements of M.G.L. c.93A §9. Defendants, via their counsel, denied Plaintiff's claims and did not offer any form of settlement.

WHEREFORE, Plaintiff, demands judgment against Defendants for compensatory damages together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

PRAYERS FOR RELIEF

WHEREFORE, Plaintiff prays for the following relief:

A. Judgment in favor of Plaintiff and against Defendants, for damages in such amounts as may be proven at trial;

B. Compensation for both economic and non-economic losses, including but not limited to medical expenses, disfigurement, pain and suffering, mental anguish and emotional distress, in such amounts as may be proven at trial;

C. Restitution and disgorgement of all revenue that Defendants have obtained through the manufacture, marketing, sale and administration of the Pinnacle Devices;

D. Attorneys' fees and costs where applicable;

E. Pre-and post-judgment interest; and

F. Any and all further relief, both legal and equitable, that the Court may deem just and proper.

JURY DEMAND

Plaintiff hereby demands a trial by jury.

Respectfully submitted,

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DATED: